

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
21 October 2004 (21.10.2004)

PCT

(10) International Publication Number
WO 2004/089187 A3

(51) International Patent Classification⁷: G01N 33/00, 33/53, 33/558

C12Q 1/68,

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2004/010169

(22) International Filing Date: 1 April 2004 (01.04.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/459,878 1 April 2003 (01.04.2003) US

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(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

24 March 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: CARIES RISK TEST FOR PREDICTING AND ASSESSING THE RISK OF DISEASE

(57) Abstract: Provided are methods, test devices, and diagnostic kits for predicting, assessing, and diagnosing the risk of a disease using salivary analysis. The method comprises providing a whole (unfractionated) saliva sample from a subject; contacting an aliquot of said saliva with one or more lectins under conditions that allow said one or more lectins to bind to a lectin-binding component of said saliva; detecting the amount of bound lectin; and comparing the amount of bound lectin to the amount known to bind a saliva sample from a control patient, to predict the risk of a disease in the subject. Also provided are methods for reducing the risk of a disease and a method for assessing the risk of the disease at a defined level.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/10169

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; G01N 33/00, 33/53, 33/558;
US CL : 435/6, 7.1; 436/514, 518;

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 435/6, 7.1; 436/514, 518;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	STEINFELD et al., "Labeled Neoglycoproteins and Human Lectins as Diagnostic and Potential Functional Markers in Salivary Glands of Patients with Sjogren's Syndrome." The Journal of Rheumatology, 2000, Vol.27, pages 1910-1916. Abstract Only, see entire document.	1, 3, 4, 5, 9, 26, and 31
Y	BELCE et al., "Evaluation of salivary sialic acid level and Cu-Zn superoxide dismutase activity in type 1 diabetes mellitus." Tohoku Journal of Experimental Medicine, November 2000, Vol.192, No.3, pages 215-225. Abstract Only. See entire document.	2, 6-8, 10-25, 27-30, and 31-60
Y	ASTOR et al., "Xerostomia: A prevalent condition in the elderly.", ENT-Ear, Nose, & Throat Journal, July 1999, pages 476-479., See entire document.	2
Y	NIELSEN et al., "Differential Expression of Human High-molecular weight Salivary Mucin (MG1) and Low-molecular weight Salivary mucin (MG2)." Journal of Dental Research, November 1996, Vol.75, No.11, pages 1820-1826, See entire document.	10-13 and 27-30
Y	US 5,585,241 A (LINDMO) 17 December 1996, see entire document.	14-17 and 20
Y	US 5,585,241 A (LINDMO) 17 December 1996, see entire document.	18-19 and 21-26

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

29 October 2004 (29.10.2004)

Date of mailing of the international search report

12 JAN 2005

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US04/10169**C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,436,721 B (KUO et al.) 20 August 2002, See entire document.	31-60

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/10169

Continuation of B. FIELDS SEARCHED Item 3:
East and West patent database search.
STN- biosis, caplus, embase, medline, cancerlit, japiro